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EXAMINER

SWEET, THOMAS

ART UNIT PAPER NUMBER

3738

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/751,749

Applicant(s)

HEATH, KEVIN R.

Examiner

Thomas J. Sweet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 31-38 have been considered but are moot in view of the new ground(s) of rejection. The prior art of record is still applicable.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/924275 and prior applications, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Accordingly, claims 39-46 are not entitled to priority to the prior application.

Regarding claim 39, the disclosure does not support the terminology of "third metal portion". The disclosure mentions layers and coatings which could be described as portions, however these layers or coating are not described as metal such that a third portion would be

enabled or reasonably recognized by one of ordinary skill in the art at the time the invention was made beyond the two layers of metal disclosed.

Regarding claims 40-46, the only disclosure of three portions is to “three or more layers” of successively less dense outer material cladded on a filament which therefore does not support portions of the same material as required by claim 40.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “third metal portion” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The amendment filed 03/04/2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

“the third metal portion is formed of said first metal” of claim 40 is not disclosed. As discussed above with regard to priority, the disclosure is contrary to more than one layer of the same material.

A “third metal portion” of claims 39-46 is not disclosed such that one of ordinary skill in the art would recognize possession the claimed limitation. The only distinct “portions” disclosed deal with layers of different densities (metal is not specifically disclosed), since other materials specifically disclosed as a layer (coatings, such as fluorocarbons), one would not reasonable recognize a third metal portion as the invention. Since, alloys can be formed by two or more metals, the passage “at least two different metals” does not support a third metal portion.

A third metal portion associated with a sheet of claim 46 is not supported. The disclosure of a third layer is directed to a filament.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As discussed above with respect to the specification objection, the claims do not reasonably convey to one of ordinary skill in the art that the application had possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims refer to the term "portion" which is not clear from the disclosure which discloses layers and coatings, but portion is broader which therefore makes the scope of the claim indiscernible in light of the specification.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

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with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23 of U.S. Patent No. 6287331. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 23 encompasses the limitations of claim 39.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs et al (US 637123). Jacobs et al discloses a medical device, comprising: an implantable medical stent (fig. 1) expandable by a balloon to fix the stent in a predetermined position in contact with a body lumen wall by plastic deformation(col 4, lines 8-24), said stent formed of a metal member (fig. 2) in the form of a tube (as seen in fig. 1), said metal member having a cross-sectional thickness of about 0.0075 inch or less (col 4, line 38) and formed of at least two different metals (tantalum and stainless steel), said metal member including across said thickness a first metal portion (stainless steel, 18), a second portion (tantalum, 20), and a third metal portion (stainless steel, 22), wherein the first metal portion is formed of a first metal and the second metal portion is formed of a second, different metal, and wherein the density of the second metal is greater than the density of the first metal (tantalum is denser than stainless steel) for enhancing the

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radiopacity of the metal member (inherent, based on the structure being the same as the present invention).

With regard to claim 44, a non-metal coating on an outer surface of said metal member is inherent since chromium oxide forms as a coating on all stainless steel.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45 and 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over by Jacobs et al. by Jacobs et al discloses a stent as discussed above. However, Jacobs et al does not disclose as polymer coating on the stent. It is common knowledge in the prior art to coat a stent with a drug polymer for the purpose of providing treatment material at the location of the stent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the stent of Jacobs et al with a drug polymer in order to provide treatment material at the location of implantation.

With regard to claim 46, the metal member is a composite sheet form member configured in the form of a tube (as shown by figs. 1 and 2).

Claims 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess (US 5,197,978). Hess discloses a medical device, comprising: an implantable medical stent (fig. 8)

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expandable by a balloon to fix the stent in a predetermined position in contact with a body lumen wall by plastic deformation (figs. 1-3), said stent formed of a metal member in the form of a tube (fig. 8), said metal member having a cross-sectional (at # 44) and formed of at least two different metals (shape memory alloy- abs and tantalum- col 8, line 37), said metal member including across said thickness a first metal portion (shape memory alloy, the inner wall), a second portion (44- tantalum- col 8, line 37), and a third metal portion (42- shape memory alloy, the outer wall), wherein the first metal portion is formed of a first metal and the second metal portion is formed of a second, different metal, and wherein the density of the second metal is greater than the density of the first metal (tantalum is denser than a shape memory alloy such as Nitinol) for enhancing the radiopacity of the metal member (inherent since this is the structure of the present invention). However, Hess remains silent as to the thickness of the wall (about 0.0075 inch or less). It is common knowledge in the prior art to make the stent wall as thin as possible on the order of 0.005 inch or 0.1 mm for the purpose of supporting the vessel wall but not interfering with the flow of blood. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the wall of Hess on the order of thickness of about 0.005 inches or about 0.1mm in order to supporting the vessel wall but not interfering with the flow of blood.

With regard to claim 40, the third metal portion is formed of said first metal (outer and inner surfaces of memory alloy).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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